

UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

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BEFORE THE ADMINISTRATOR

ENVIRONMENTAL PROTECTION
AGENCY-REGION VII
REGIONAL HEARING CLERK

In the Matter of

ABBOTT LABORATORIES
McPherson, Kansas

Respondent

Proceedings under Sections 308(a)
and 309(a)(3) of the Clean Water Act,
33 U.S.C. §§ 1318(a) and 1319(a)(3).

Docket No. CWA-07-2003-0013

FINDINGS OF VIOLATION,
ORDER FOR COMPLIANCE

I. PRELIMINARY STATEMENT

1. The following FINDINGS OF VIOLATION are made and ORDER FOR COMPLIANCE is issued pursuant to the authority vested in the Administrator of the United States Environmental Protection Agency ("EPA"), by Sections 308(a) and 309(a)(3) of the Clean Water Act ("CWA"), 33 U.S.C. §§ 1318(a) and 1319(a)(3), as delegated by the Administrator to the Regional Administrator, EPA Region 7, and further delegated to the Director, Water, Wetlands and Pesticides Division, EPA, Region 7.

2. The Respondent is Abbott Laboratories.

II. STATUTORY AND REGULATORY BACKGROUND

3. Section 301(a) of the CWA, 33 U.S.C. § 1311(a), prohibits the discharge of pollutants from a point source into navigable waters of the United States, except in compliance with, inter alia, Sections 307 and 402 of the CWA, 33 U.S.C. §§ 1317 and 1342. Section 402 provides that pollutants may be discharged only in accordance with the terms of a National Pollutant Discharge Elimination System ("NPDES") permit issued pursuant to that Section. Section 307 of the CWA, in pertinent part, authorizes the EPA to establish pretreatment standards for introduction of pollutants into publicly owned treatment works ("POTW").

4. Pursuant to Section 307(b) of the CWA, 33 U.S.C. § 1317(b), EPA promulgated regulations codified at 40 C.F.R. Part 403, entitled the General Pretreatment Regulations. These regulations control the introduction of pollutants into POTWs which may pass through or interfere with treatment processes of such treatment works or which may contaminate sewage sludge.

5. The Kansas Department of Health and Environment ("KDHE") is the state agency with the authority to administer the federal NPDES program in Kansas pursuant to Section 402 of the CWA, 33 U.S.C. § 1342, the implementing regulations, and a Memorandum of Understanding between EPA and KDHE.

6. KDHE is not approved to administer a state Pretreatment program in Kansas pursuant to Section 402 of the CWA and its implementing regulations. Consequently, in Kansas, EPA remains the Approval Authority as defined by 40 C.F.R. § 403.3(c).

7. The City of McPherson, Kansas (hereafter "City") has an approved POTW Pretreatment program, pursuant to 40 C.F.R. § 403.8. EPA approved the POTW Pretreatment program on or about October 23, 1983.

8. Pursuant to Section 309 of the CWA, 33 U.S.C. § 1319, EPA maintains concurrent enforcement authority with authorized states, including Kansas, for violations of state issued NPDES permits. Also pursuant to Section 309 of the CWA, EPA maintains concurrent enforcement authority for violations of Pretreatment program requirements, including those relating to the City's approved POTW Pretreatment program.

III. FINDINGS OF FACT

9. Respondent is incorporated in the State of Illinois, and is registered to do business in the State of Kansas.

10. Respondent is a "person" within the meaning of Section 502(5) of the CWA, 33 U.S.C. § 1362(5).

11. At all times relevant, Respondent was, and still is, the owner and/or operator of a pharmaceutical manufacturing facility located at 1776 North Centennial Drive, McPherson, Kansas 67460 (the "Facility").

12. The City of McPherson, Kansas (hereafter "City") owns and operates a POTW in McPherson, Kansas. The City's POTW includes a wastewater treatment plant and sewage collection system, which receives wastewater from various domestic and non-domestic sources.

13. The City's POTW is a "point source" that "discharges pollutants" into Dry Turkey Creek, as these terms are defined by Section 502(14, 12) of the CWA, respectively, 33 U.S.C. § 1362(14, 12).

14. Dry Turkey Creek is a tributary of Turkey Creek, which is a tributary of the Little Arkansas River, which in turn is a tributary of the Arkansas River.

15. Dry Turkey Creek is considered "navigable waters" of the United States, as defined by Section 502(7) of the CWA, 33 U.S.C. § 1362(7).

16. Respondent discharges process wastewater from the Facility into the City's POTW, and therefore is an "industrial user", as defined by 40 C.F.R. § 403.3(h).

17. The Facility's process wastewater is a "pollutant" as defined by Section 502(6) of the CWA, 33 U.S.C. § 1362(6).

18. Respondent is subject to the General Pretreatment Regulations at 40 C.F.R. Part 403.

19. On or about October 14, 1997, NPDES Permit EPA No. KS0036196 (the "NPDES Permit") was issued to the City by KDHE pursuant to the authority of Section 402 of the CWA, 33 U.S.C. § 1342. On or about August 27, 2002, the NPDES Permit was renewed by KDHE, effective September 1, 2002, with modifications.

20. The NPDES Permit contains limitations for discharges of effluent from the City's POTW to Dry Turkey Creek.

21. The NPDES Permit contains a POTW discharge limit for, among other pollutants, fecal coliform, expressed as the number of colonies present per 100/ml of effluent, based on a monthly geometric average. Pursuant to the terms of the NPDES Permit, this limit went into effect on June 1, 1999, and is established at 200 colonies/100ml.

22. In or about July 2000, Pretreatment Permit No. 01 (the "Pretreatment Permit") was issued to Respondent by the City pursuant to its approved POTW Pretreatment program. The Pretreatment Permit has an effective date of July 15, 2000.

23. The Pretreatment Permit contains limitations for discharges of effluent from Respondent's Facility to the City's POTW.

24. The Pretreatment Permit prohibits the discharge of any wastewater containing any substance prohibited in accordance with the City's Ordinance No. 2368. Section 15-429(h)(4) of Ordinance No. 2368 prohibits the discharge of any pollutants released at a flow rate and/or pollutant concentration which a user knows or has reason to know will cause interference to the wastewater disposal system. Both the Pretreatment Permit and Ordinance No. 2368 define "interference" as the inhibition or disruption of the wastewater treatment process or operations which contributes to a violation of any requirement of the City's NPDES permit.

25. Pursuant to the General Pretreatment Regulations at 40 C.F.R. § 403.5(a), users are prohibited from introducing pollutants into a POTW which result in the "pass through" of pollutants through the POTW, or "interference" with the operations of the POTW.

26. Definitions for "interference" and "pass through" are set forth at 40 C.F.R. § 403.3(i) and (n), respectively. Specifically:

- a. "Interference" is defined, in pertinent part, as a discharge of pollutants, which alone or in conjunction with other sources, inhibits or disrupts the treatment processes or operations of a POTW, and which therefore is a cause of a violation of any requirement of a POTW's NPDES permit; and
- b. "Pass through" is defined, in pertinent part, as a discharge of pollutants which exits a POTW into waters of the United States in quantities or concentrations which, alone or in conjunction with other sources, is a cause of a violation of any requirement of a POTW's NPDES permit.

27. In or around February 2000, the City installed and began operating an ultraviolet (UV) light system at the POTW to disinfect the wastewater with the goal of meeting the fecal coliform limits in the NPDES Permit. Such UV systems are regularly used in the wastewater treatment industry, and are designed to operate by reducing levels of fecal coliform present in wastewater by exposing it to the UV light generated by the system. In particular, such systems operate by using the "C" band of UV light (UV-C) to destroy the fecal coliform.

28. Subsequent to the start up of the UV system, sampling of the POTW's effluent indicated levels of fecal coliform exceeding the limits established in the NPDES Permit. As a result, the City investigated the problem and determined that the POTW is receiving wastewater containing substances ("UV inhibitors"), which, when mixed with the other wastewater entering the POTW, are inhibiting the ability of the UV light to penetrate the wastewater and thus destroy the fecal coliform.

29. In or about September 2000, the City initiated a city-wide study of its sewer system to determine the sources of the UV inhibitors. In doing so, the City methodically tested each of the five branches of the sewer system for the wastewater's UV transmissivity, which is the wastewater's ability to allow UV light, similar to that used by the POTW's UV system, to pass through. The testing demonstrated that Respondent's Facility is a major contributor of UV inhibitors to the POTW. On or about October 11, 2000, the City informed Respondent of the results of the testing, and asked Respondent to determine which substances from the Facility were causing the UV inhibition.

30. On or about April 2, 2002, KDHE and the City entered into a Consent Order which addressed the City's violations of the fecal coliform limits contained in the NPDES Permit. The Consent Order, among other things, temporarily revises the fecal coliform monthly geometric average limit in the NPDES Permit to 800 colonies/100ml, for the one-year period from May 1, 2002 through April 30, 2003, and provides for the limit to revert back to 200 colonies/100ml on May 1, 2003.

IV. FINDINGS OF VIOLATION

Paragraphs 9 through 30 above are incorporated herein by reference.

31. The City violated the fecal coliform limits of the NPDES Permit on no less than the following occasions, as indicated by the table below.

Month/Year	City POTW's Fecal Coliform Discharge - Colonies/100ml, Monthly Geometric Avg. (200 Colonies/100ml - NPDES Permit Limit)
February, 2001	789
March, 2001	335
August, 2001	681
November, 2001	230
February, 2002	342
March, 2002	228

32. On the occasions described in the table above, the Facility's wastewater discharges to the POTW contained significant amounts of UV inhibitors, and thus caused the pass through of fecal coliform from the POTW, and/or the interference of the POTW's treatment processes or operations in regard to its ability to disinfect the wastewater.

33. The occasions of pass through and/or interference described in paragraph 31 and the table above are violations, by Respondent, of the General Pretreatment Regulations at 40 C.F.R. § 403.5(a)(1), and Sections 301(a) and 307(d) of the CWA, 33 U.S.C. §§ 1311(a) and 1317(d).

34. The occasions of pass through and/or interference described in paragraph 31 and the table above are also violations, by Respondent, of Section 15-429(h)(4) of Ordinance No. 2368, and thus Respondent's Pretreatment Permit.

V. ORDER FOR COMPLIANCE

Based on the Findings of Violation set forth above, and pursuant to Sections 308(a) and 309(a)(3) of the CWA, 33 U.S.C. §§ 1318(a) and 1319(a)(3), Respondent is hereby ORDERED to take the following actions to eliminate interference and pass through caused by its discharges of UV inhibiting pollutants to the City of McPherson's POTW:

UV-C Light Inhibitors Management Plan

35. No later than thirty (30) days following the receipt of this Order, Respondent shall submit to EPA the following:

A. A list of all substances used and/or stored at the Facility which are known or suspected to be a UV-C light inhibitor. This list shall include, for each such substance: (i) the quantities stored at the Facility; (ii) a description of the product and/or processes that use the substance; (iii) the typical frequency and duration of the manufacturing processes for the products which use the substance; (iv) the amount of each substance used per batch for each process which uses it; (v) the estimated average amount of the substance used Facility-wide per month (for all uses combined); and (vi) where available, UV-C transmissivity data for the substance, both in undiluted and diluted forms.

B. A draft Facility-wide management plan for investigating, controlling and limiting the discharge of each UV-C inhibiting substance identified pursuant to subparagraph A above, to the City's POTW, regardless of path of entry into the City's sewer system (e.g. process wastewater discharge, other controlled releases, spills, etc.). The plan shall contain, among other things, a proposed schedule setting forth a time line for implementation of the plan at the Facility.

36. EPA will review the draft management plan and provide comments to Respondent. Within twenty-one (21) days from its receipt of EPA's comments, Respondent shall revise the plan in consideration of EPA's comments, and submit the revised plan to EPA for its approval. EPA will then either approve the plan, approve the plans with modifications, or provide additional comments to Respondent for its further revision of the plan prior to EPA approval. If further revision is required, within twenty-one (21) days from its receipt of EPA's comments, Respondent shall once again revise the plan in consideration of EPA's comments, and submit the revised plan to EPA for its approval. If EPA approves the plan, or approves the plan with modifications, Respondent shall thereafter implement the plan according to the schedule and terms therein.

Monitoring

37. Within ten (10) days of the effective date of this Order, Respondent shall designate a sampling location at a point within Respondent's discharge stream to the City's POTW that is capable of obtaining representative measurements and samples of all discharges of process wastewater from the Facility into the POTW (This sampling location is hereafter referred to as "Plant Flow").

38. Within ten (10) days of the effective date of this Order, Respondent shall hereafter monitor for the following parameters, at the specified location and frequencies:

<u>Parameters</u>	<u>Locations</u>	<u>Frequency</u>	<u>Sample Type</u>
Flow (gpd)	Plant Flow	Continuous	Meter
UV-C Transmissivity	Plant Flow	Continuous	In Line Spectrofotometer

39. Respondent shall conduct the monitoring described in paragraph 38 above, until notified in writing by EPA that such monitoring is no longer required.

40. Respondent shall handle and preserve all collected samples and laboratory analyses of samples required by this Order in accordance with the requirements of 40 C.F.R. Part 136.

41. Respondent shall ensure that all samples and measurements taken pursuant to this Order shall be representative of the volume and nature of the Facility's discharge. All samples shall be taken at the monitoring location specified in this Order. All equipment used for sampling and analysis must be routinely calibrated, inspected and maintained to ensure their accuracy.

42. For all flow measurements required by this Order, Respondent shall employ a flow measurement device and method that are consistent with accepted scientific and industry practices to ensure the accuracy and reliability of measures of the volume of monitored discharges. Any devices selected shall be capable of measuring flows with a maximum deviation of less than 10 percent from true discharge rates. The device shall be installed, calibrated, and maintained to ensure that the accuracy of measurements are consistent with the accepted capability of the installed device.

43. The monitoring location shall not be changed without written approval by EPA. Further, in the event that EPA determines that the measurement and/or analytical devices and/or methods used by Respondent are inaccurate or unreliable, EPA may direct Respondent to employ specific measurement devices or methods capable of providing representative sampling and results.

44. For each day's sampling or measurements at the sampling location, Respondent shall complete a Sampling Report that contains the following information for all measurements,

sampling and/or analyses taken during that day:

- a. The date, exact place, time and methods of sampling or measurements, and sample preservation techniques or procedures;
- b. Who performed the sampling or measurements;
- c. The date(s) analyses of samples were performed;
- d. Who performed the analyses;
- e. The analytical techniques or methods used to analyze samples; and
- f. The results of such analyses submitted electronically in spreadsheet format.

Monthly Reporting

45. Beginning with the first full calendar month following the effective date of this Order, Respondent shall submit to EPA a Monthly Monitoring Report, which shall be submitted on or before the tenth day of each month. The Monthly Monitoring Report shall contain the following information:

- a. A summary of the results of all samples and monitoring taken by Respondent during the prior calendar month (reporting period); and
- b. Copies of all Sampling Reports for the prior calendar month.

Additional Reporting

46. Respondent shall notify EPA at least ninety (90) days prior to any facility expansion, production increase, or process modifications which may result in new or increased discharges or changes in the nature of the discharge from Respondent's facility.

47. Respondent shall notify EPA at least ten (10) days prior to implementing any planned operational changes at its facility which may result in increased UV-C light inhibition in the Facility's wastewater effluent to the POTW.

48. If Respondent's facility experiences operational upset that jeopardizes the City POTW's compliance with its NPDES Permit, Respondent shall inform the City as soon as possible, but no later than twenty four (24) hours after becoming aware of the upset. Additionally, Respondent shall provide written notification to EPA within five (5) days of the upset that contains the following information: A description of the upset, including the cause(s) and duration thereof and the upset's impact on the POTW's compliance with its NPDES Permit

and Respondent's compliance with the EPA-approved UV-C Light Inhibitors Management Plan.

Submissions

49. All notifications and documents required to be submitted to EPA by this Order shall be submitted by mail to Ms. Cynthia Sans, at the following address:

United States Environmental Protection Agency-Region 7
NPDES and Facilities Management Branch
901 N. 5th Street
Kansas City, Kansas 66101

50. A copy of all notices, documents and other information required to be submitted to EPA pursuant to this Order shall be provided to both KDHE and the City of McPherson, addressed to the following:

Mr. Karl Mueldener, Director
Kansas Department of Health and Environment
Division of Environment
Bureau of Water
1000 S.W. Jackson St.; Suite 420
Topeka, KS 66612-1367; and

Mr. Steve Gorszczyk, Superintendent
McPherson Wastewater Treatment
400 E. Kansas Ave.
P.O. Box 1008
McPherson, KS 67460

51. All submissions made by Respondent to EPA pursuant to the requirements of this Order shall contain the following certification that is signed by a responsible corporate officer or plant manager:

"I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing submissions of false information."

Effect of Compliance with the terms of this Order for Compliance

52. Compliance with the terms of this Order shall not relieve Respondents of liability for, or preclude EPA, the State of Kansas, and/or the City of McPherson, from initiating an administrative or judicial enforcement action to recover penalties for any violations of the CWA, or seeking additional injunctive relief, pursuant to Section 309 of the CWA, 42 U.S.C. § 1319.

53. This Order shall not constitute a permit under the CWA. Compliance with the terms of this Order shall not relieve Respondent of its responsibility to obtain and comply with any required local, state and/or federal permits.

54. EPA may subsequently amend this Order in accordance with the authority of the CWA. For example, EPA may amend this Order to address additional noncompliance with the CWA, including but not limited to additional non-compliance with the requirements of Section 402 of the CWA. In the event of any such subsequent amendment to this Order, all requirements for performance of this Order not affected by the amendment shall remain as specified by this Order.

Access and Requests for Information

55. Nothing in this Order shall limit EPA's right to obtain access to and inspect Respondent's Facility, and/or to request additional information from Respondent, pursuant to the authority of Section 308 of the CWA, 33 U.S.C. § 1318.

Severability

56. If any provision or authority of this Order or the application of this Order to Respondent is held by federal judicial authority to be invalid, the remainder of this Order shall remain in full force and effect and shall not be affected by such a holding.

Waiver

57. This Order does not constitute a waiver or a modification of any requirements of the CWA, 33 U.S.C. § 1251 et seq., all of which remain in full force and effect. EPA retains the right to seek any and all remedies available under Sections 309(b, c, d or g) 33 U.S.C § 1319(b, c, d or g), for any violation cited in this Order. Issuance of this Order shall not be deemed an election by EPA to forgo any civil or criminal action to seek penalties, fines, or other appropriate relief under the CWA for any violation whatsoever.

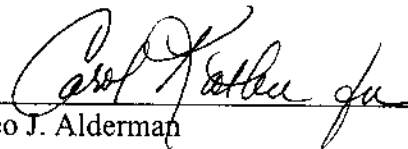
Effective Date

58. The terms of this Order shall be effective and enforceable against Respondent upon its receipt of the Order.

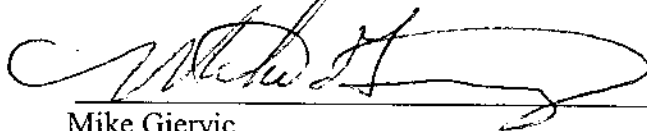
Termination

59. This Order shall remain in effect until a written notice of termination is issued by an authorized representative of EPA. Such notice shall not be given until all of the requirements of this Order have been met.

Issued this 1st day of November, 2002.



Leo J. Alderman
Director
Water, Wetlands and Pesticides Division
U.S. Environmental Protection Agency, Region 7



Mike Gieryic
Assistant Regional Counsel
U.S. Environmental Protection Agency, Region 7

CERTIFICATE OF SERVICE

I certify that on the date indicated below, I hand delivered the original and one true copy of this Findings of Violation and Order for Compliance to the Regional Hearing Clerk, United States Environmental Protection Agency, 901 North 5th Street, Kansas City, Kansas 66101.

I further certify that on the date noted below I sent by certified mail, return receipt requested, a true correct copy of the same to the following:

The Corporation Company, Inc.
Registered Agent for
Abbott Laboratories
515 S. Kansas Ave.
Topeka, KS 66603

Hon. William Goering
Mayor of the City of McPherson
400 E. Kansas Ave.
McPherson, KS 67460

Mr. Karl Mueldener, Director
Kansas Department of Health and Environment
Division of Environment
Bureau of Water
1000 S.W. Jackson St.; Suite 420
Topeka, KS 66612-1367

November 1, 2002
Date

Cynthia Sams